IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANDREA PERRY ET AL. : CIVIL ACTION

:

V.

NOVARTIS PHARMACEUTICALS

CORPORATION : NO. 05-5350

#### MEMORANDUM

Dalzell, J. January 12, 2006

Andrea and George Perry's son, Andreas, suffered from eczema, a type of skin inflammation. To treat Andreas's eczema, his parents bought and gave him Elidel, a drug that Novartis designed, manufactured, and sold. Plaintiffs allege that in addition to treating skin inflammation, Elidel causes cancer, and, in October of 2003, a doctor diagnosed Andreas with lymphoma "[a]s a result of using" it. Compl. ¶ 27.

On October 12, 2005, Andrea and George Perry, individually and for their son, sued Novartis for strict liability (count one), negligence (count two), and deceit and fraud (count three). Before us is Novartis's motion to dismiss count three because, under Fed. R. Civ. P. 9(b), plaintiffs have pleaded it with insufficient specificity. While we agree and

Eczema is the clinical name for dermatitis, or "[s]uperficial skin inflammation, characterized histologically by epidermal edema and clinically by vesicles (when acute), poorly marginated redness, edema, oozing, crusting, scaling, usually pruritus, and lichenification caused by scratching or rubbing." The Merck Manual of Diagnosis and Therapy 786 (Mark H. Beers, M.D. et al eds., 17th ed. 1999). There are eight primary types of dermatitis: contact, atopic, seborrheic, nummular, chronic of the hands and feet, generalized exfoliative, stasis, and licen simplex chronicus. Id. at 786-93.

will grant Novartis's motion, we will nevertheless allow plaintiffs to file an amended complaint that satisfies Rule 9(b).

# I. The Complaint

In the complaint, plaintiffs allege that Novartis is a pharmaceutical company that designed, manufactured, and marketed Elidel as a safe and effective drug to treat eczema. Compl. ¶ 5. When it marketed Elidel, plaintiffs claim that Novartis purposely or, at the least, negligently downplayed Elidel's health risks.

Id. ¶ 6. Chief among those risks, Elidel "has been shown to carry a serious risk of cancer." Id. Despite allegedly knowing about this risk, Novartis "encouraged the belief that Elidel had been tested and medically proven safe and effective for use with adults and children." Id. Specifically, plaintiffs aver that Novartis materially misrepresented that clinical and laboratory tests proved Elidel safe. Id. ¶ 23. Novartis is also said to have materially omitted key safety information, most notably that Elidel could cause cancer. Id. ¶ 26.

Based on these claimed material misrepresentations and omissions, Andreas's parents bought Elidel for their son and gave it to him. Id.  $\P$  24. "[A]s a result of using Elidel," plaintiffs report that in October of 2003, a doctor diagnosed Andreas with lymphoma. Id.  $\P$  7. The Perrys state that had they known the truth about Elidel, they would never have bought or administered the drug. Id.  $\P$  27.

# II. Governing Law

Under Rule 12(b)(6), we may dismiss a complaint for "failure to state a claim upon which relief can be granted." In addition to taking all factual allegations as true, we must draw all reasonable inferences in plaintiffs' favor. See In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 397 (3d Cir. 2000). Rule 12(b)(6) permits dismissal only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957).

Generally, a court must evaluate a complaint's sufficiency through the lens of Rule 8(a). Rule 8(a) requires only notice pleading. This means that a plaintiff need only "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." Conley, 355 U.S. at 47.

This general rule is subject to an exception when a plaintiff alleges fraud. Fraud allegations trigger Rule 9(b), which raises the bar by requiring that "the circumstances constituting fraud . . . shall be stated with particularity."

This language requires plaintiffs to identify (1) the deceiver, (2) the victim, and (3) the "general content" of the misrepresentation. Lum v. Bank of Am., 361 F.3d 217, 224 (3d Cir. 2004). In addition, plaintiffs must (4) either plead the "date, place or time" of the fraud, or, through alternative means, "inject[] precision and some measure of substantiation

into the fraud allegations." Id. This heightened standard notifies defendants of "the precise misconduct with which they are charged" and "safeguard[s] [them] against spurious charges of immoral and fraudulent behavior." Seville v. Southmost Machinery Corp., 742 F.2d 786, 791 (3d Cir. 1984).

Our Court of Appeals has articulated a second way in which plaintiffs may satisfy Rule 9(b). When "the factual information is peculiarly within the defendant's knowledge or control," In re Burlington Coat Factory, 114 F.3d 1410, 1434 (3d Cir. 1997) (citing Shapiro v. UJB Fin. Corp., 964 F.2d 272, 285 (3d Cir. 1992)), plaintiffs may satisfy Rule 9(b) by: (1) "delineat[ing] at least the nature and scope of plaintiffs' effort to obtain, before filing the complaint, the information needed to plead with particularity," UJB, 964 F.2d at 285, and (2) "accompany[ing] their legal theory with factual allegations that make their theoretically viable claim plausible." Burlington, 114 F.3d at 1418; see also In re Rockefeller Ctr. Props., Inc. Sec. Litiq., 311 F.3d 198, 216 (3d Cir. 2002). This rule reflects the sensitivity that courts must exercise if applying Rule 9(b) too harshly could "permit sophisticated defrauders to successfully conceal the details of their fraud."

In <u>Seville Indus. Machinery Corp. v. Southmost</u>
<u>Machinery Corp.</u>, 742 F.3d 786 (3d Cir. 1984), for example, our
Court of Appeals found sufficient precision when the plaintiffs
incorporated into the complaint a list identifying "with great
specificity the pieces of machinery that were the subject of the
alleged fraud" and "divided this list into five 'exhibits' and
identified which pieces of equipment were the subject of which
alleged fraudulent transaction." Id. at 791.

Burlington, 114 F.3d at 1418.

# III. Legal Analysis

Because plaintiffs claim that Novartis defrauded them,
Rule 9(b)'s heightened standard applies. Count three cannot
withstand scrutiny under either standard set forth above.

Beginning with the first, plaintiffs fail to plead the date, place, or time of the fraud. They also neglect to "inject[] precision and some measure of substantiation into their fraud allegations." Lum, 361 F.3d at 224. To be sure, plaintiffs do describe the deceiver, Novartis, the victim, themselves, and even the general content of the misrepresentation: that Elidel was safe. But they simply fail to weave specific facts into these general allegations, thereby violating Rule 9(b)'s plain terms. Moreover, if Andreas's parents really were defrauded, one would expect that they would be able to describe when and how, without having to resort to discovery. Cf. Fed. R. Civ. P. 11(b)(3).

Under the alternative standard our Court of Appeals has enunciated, plaintiffs fail to plead that the factual information they need is peculiarly within Novartis's knowledge or control. Plaintiffs also neglect to delineate their efforts, if any, to obtain the information needed to plead with particularity. Given the plethora of sources available today -- e.g., websites, the Food and Drug Administration, its European counterparts, etc. -- it simply will not do in this kind of litigation to say, as

Brandt does in <u>The Big Lebowski</u>, "Well, dude, we just don't know."

# IV. Conclusion

Joel Coen, <u>The Big Lebowski</u> (PolyGram Filmed Entertainment/Working Title Films 1998).